DEPARTMENT OF HEALTH & **HUMAN** SERVICES

Public **Health Service**

Food and Drug Administration
Rockville MD 20857

MAR 16 1999

NDA 17-963/S-051

Novartis Pharmaceuticals Corporation
Attention: Ms. Donna M. Vivelo
59 Route 10
East Hanover, NJ 07936-1080

Dear Ms. Vivelo:

Please refer to your supplemental new drug application dated October 27, 1998, received October 30, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lopressor (metoprolol tartrate) 50 and 100 mg Tablets.

This supplemental new drug application provides for final printed labeling revised as follows:

1. The PRECAUTIONS/Laboratory Tests section has been deleted and the following has been added to the ADVERSE REACTIONS/Gastrointestinal section:

   Post-marketing experience reveals very rare reports of hepatitis, jaundice and non-specific hepatic dysfunction. Isolated cases of transaminase, alkaline phosphatase, and lactic dehydrogenase elevations have also been reported.

2. The following have been deleted from the HOW SUPPLIED/Tablets 50 mg section:

   Gy-Pak – One Unit
   12bottles-60 tablets each ---- ---- - ----NDC0028-0051-73
   12bottles-100 tablets each ----------NDC 0028-005l-65

3. The following have been deleted from the HOW SUPPLIED/Tablets 100 mg section:

   Gy-Pak – One Unit
   12 bottles – 60 tablets each ---------- NDC 0028-007 l-73
   12 bottles – 100 tablets each ---------- NDC 0028-007 l-65

4. Under the HOW SUPPLIED section, the following has been changed from:

   Samples, when available, are identified by the word SAMPLE appearing on each tablet.
   Store between 59°-86° F (15°-30°C).

   to:

   Store between 15°-30° C (59°-86°F).

5. The following statement has been added to the end of the **HOW SUPPLIED** section:

Do not store above 30°C (86°F).

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling included in your October 27, 1998 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 3 14.80 and 314.81.

If you have any questions, please contact:

Ms. Zelda McDonald
Regulatory Health Project Manager
(301) 594-5333

Sincerely yours,

Raymond J. M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research